

REMARKS

Claims 21-36 are presently pending in the case. Though Applicant disagrees with the rejection of claims 21, 28, and 32 and reserves the right to pursue the claims in a continuing application, claims 21, 28 and 32 have been amended in order to expedite prosecution. Support for the amendment can be found throughout the specification as originally filed, for example on page 10 line 24 through page 11 line 20.

Reconsideration of the present case in view of the remarks herein is requested.

Claim rejections under 35 USC 103(a)

The Examiner rejected claims 21-31 under 35 USC 103(a) as being unpatentable over European Patent Application EP 0 808 635 to Howlett (hereinafter "Howlett"). The rejection is traversed.

Howlett does not render Applicant's invention as set forth in claim 21 unpatentable because it does not teach or suggest all features positively recited in the claim. Claim 21 is to a device for controlling the delivery of an aerosolized active agent to the lungs comprising, inter alia, a valve that provides a high flow resistance of at least $0.4 \text{ (cm H}_2\text{O)}^{1/4}$ /SLM at the onset of a patient's inhalation. In contrast, Howlett discloses a device where its flow resistance at the onset of inhalation (as shown by the configuration shown in Figure 2) is the minimum flow resistance, and as a patient generates more pressure, the flow resistance increases. The flow resistance of the Howlett device is never lower than it is at the onset of inhalation. Thus, Howlett does not disclose or suggest a valve that provides a high flow resistance at the onset of inhalation that subsequently changes to a lower flow resistance. Since all elements of claim 21 are not taught or suggested by the reference, the claim is not rendered unpatentable by Howlett.

Furthermore, claim 21 includes other distinguishing features. For example, claim 21 recites "wherein the lower flow resistance allows for a higher flow rate through the device". In contrast, Howlett modulates the flow resistance in order to maintain "a predetermined rate regardless of patient respiratory effort". Therefore, the Howlett valve is a different type of valve

than the one being claimed by Applicant. For this additional reason, Howlett does not render claim 21 unpatentable.

Claims 22-27 depend from and include the limitations of claim 21. Therefore, Howlett does not render claims 22-27 unpatentable for at least the reasons discussed above. In addition, claim 24, for example, further recites that the high flow resistance corresponds to a flow rate of 15 liters per minute or less. Since Howlett teaches a flow rate of 30-60 liters per minute, it does not teach or suggest a flow resistance corresponding to a flow rate of 15 liters per minute or less.

Claim 28 is also not rendered unpatentable by Howlett. Claim 28 recites a valve that provides a high flow resistance at the onset of the patient's inhalation and that subsequently opens to provide a lower flow resistance which corresponds to a higher flow rate. Since Howlett does not disclose either a valve which provides a high flow resistance at the onset of inhalation or a valve which opens to provide a higher flow rate, as discussed above, Howlett does not render claim 28 unpatentable.

For at least the reasons above, the invention set forth in claim 28 is not rendered obvious by the teachings of Howlett nor are claims 29-31 which depend from claim 28. Accordingly, it is requested that the rejections be withdrawn.

The Examiner rejected claims 32-36 under 35 USC 103(a) as being unpatentable over U.S. Patent 5,577,497 to Mecikalski et al (hereinafter Mecikalski et al) in view of PCT Publication WO 97/40819 to Schultz et al (hereinafter Schultz et al). The rejection is traversed.

Mecikalski et al and Schultz et al do not render claim 32 unpatentable. Claim 32 is to a device for controlling the delivery of an aerosolized active agent comprising a valve that opens to provide a changing flow resistance. Neither Mecikalski et al nor Schultz et al disclose this feature. Thus, the references do not render claim 32 unpatentable.

Claims 33-36 depend from claim 32 and are not rendered unpatentable by Mecikalski et al and Schultz et al for at least the same reasons as the claim from which they depend.

Information Disclosure Statement

Applicant has filed a number of information disclosure statement in compliance with MPEP section 609. For example, information disclosure statements were filed on July 28, 2000, on February 26, 2001, on April 3, 2001, on August 31, 2001, on September 20, 2001, on March 5, 2002, and on October 29, 2002. Applicant included in a previous response copies of the statements and copies of the postcard returned by the Patent Office indicating that the information disclosure statements were received. Applicant request indication of the consideration of the references cited in the information disclosure statements.

Conclusion

The claims are allowable for the reasons given above. Thus, the Examiner is respectfully requested to reconsider the present rejections and allow the presently pending claims. Should the Examiner have any questions, the Examiner is requested to call the undersigned at the number given below.

Respectfully submitted,

NEKTAR THERAPEUTICS
(formerly INHALE THERAPEUTIC
SYSTEMS, INC.)

Dated: 03 DEC 03

By: Guy V. Tucker
Guy V. Tucker
Reg. No. 45,302

Please send all correspondence to:
Guy Tucker
Nektar Therapeutics
150 Industrial Road
San Carlos, CA 94070

Please direct telephone calls to:
Guy Tucker
(650) 620-5501